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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, Maryland 20857

**Re: Comments to Docket No. 97N-0135**
**Proposed Rule: Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing**

Dear Sir/Madam:

On March 5, 1998, the Food and Drug Administration (FDA) published in the Federal Register a proposed rule relating to OTC Test Sample Collection Systems for Drugs of Abuse Testing. 63 Fed. Reg. 10,792, 10,797 (1998). These comments are submitted on behalf of persons who request that the undersigned submit comments.

To date, the FDA has neither completed the rulemaking process nor accomplished the intentions expressed in the preamble to the proposed rule. In addition, positions expressed by the FDA are inadequate, unsupported, and contrary to law. Therefore, it is requested that the FDA either withdraw the proposed rule or publish a reproposal to address the deficiencies.

Irrespective of the action to be taken by the FDA, these comments are submitted to address the content of the preamble as well as the proposed rule itself. There are four areas of concern for which comments are provided. These include jurisdiction, procedure, policy, and application of statute.

97N-0135 C2

**Jurisdiction**

Unless the Test Sample Collection Systems (Test Systems) are intended for diagnosis of disease or other condition, the FDA has no lawful jurisdiction over the availability of drugs of abuse test systems. Although the definition of the term "device" in the Federal Food, Drug, and Cosmetic Act (the "Act") is remarkably broad, it applies only to products that are intended for use for the "diagnosis of disease or other conditions."[1]

The reference to "disease or other conditions" in the device definition is and has been applied to products intended for use in the health/medical care of humans or animals. For example, pregnancy is not a disease; but, it is a health and/or medical related condition for which articles to diagnose the condition are encompassed by the definition of device in the Act. A product that is designed to measure strength may be important for use by an athlete, but it is not used to diagnose a condition. However, if the same product were intended for use by a physician as part of the medical diagnosis of a muscular/neurological disease or condition, the product would be considered a device.

A product that is used for law enforcement or other non-diagnostic purposes cannot be considered a device as the term is presently defined in the Act. The reason for the existence of drugs of abuse test products is because the presence of these drugs under certain conditions is illegal. These types of products are to be used for law enforcement and compliance purposes, rather than for diagnosis. For example, tests for the illegal presence of alcohol or other drugs in the body of a driver of a motor vehicle are not intended to

[1] The FDA promulgated a regulation which would subject cigarettes and smokeless tobacco products to regulation as devices. With regard to the legal status of this "regulation," the United States Court of Appeals for the Fourth Circuit stated, "[b]y its ultra vires action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand." Brown & Williamson Tobacco Co. v. FDA, 153 F.3d 155, 176 (4th Cir. 1998). The U.S. Supreme Court granted a petition for writ of certiorari and arguments will be heard this term.

diagnose whether the driver is an alcoholic or an addict. Rather, these tests are available to law enforcement personnel to determine whether an individual is in compliance with applicable law. For those who are expected to comply with the law, it is essential that they likewise have access to products that enable them to be in compliance with the law. Whether it is:

- an interstate truck driver who is subject to testing for drugs/alcohol prior to driving;
- the social drinker who is about to drive;
- the youngster whose parents must consent for their child to undergo drug testing at a school facility in order to participate in extra curricular activities; or
- conscientious parents who are concerned for their child's well being,

the availability of these non-diagnostic products is essential to the freedom that consumers must have to make choices, in particular as this relates to compliance efforts.

Drug and alcohol test systems are not devices when the intent of these products is for educational, compliance, law enforcement, or other purposes that do not relate to diagnosis of a medical disease or condition. The FDA has no right to distort the lawful definition of the term device for the use of a product that is essential to compliance for societal and law enforcement purposes. Moreover, arbitrary efforts by the FDA to interfere with or complicate consumer access to the benefits associated with these products thwart consumer efforts to reduce and eliminate illegal use of drugs and alcohol.

To the extent that government regulation of these non-diagnostic products may be beneficial, there are federal laws administered by the Federal Trade Commission, Consumer Product Safety Commission, U.S. Postal Service, and other agencies which exist to provide adequate protection against consumer fraud or abuse. Likewise, confirmatory testing of products which provide screening results can be obtained through the 70 laboratories certified by the Substance Abuse and Mental Health Service Administration

(SAMHSA). Moreover, if a product has been cleared by the FDA for a diagnostic use there is no reason to prevent that same product from being used for a non-diagnostic, non-device use. Consequently, there is also no reason or authority for the FDA to attempt to restrict the distribution of the product whether it is used for sample collection or screening purposes.

**Procedure**

Notwithstanding the position of the undersigned that the FDA has no jurisdiction over these test systems as devices, if the FDA could establish that these products are devices, it would have to classify them with the assistance of an advisory panel of experts.

In the preamble to the proposed rule, the FDA, through its Commissioner and the Secretary of Health and Human Services, states as follows:

> "When FDA reclassifies a postamendments device on its own initiative, the agency follows the same statutory provisions and regulations that apply to reclassifications of such devices in response to a petition."

63 Fed. Reg. at 10,795. Yet, there is no reference in the preamble to the proposed rule that reflects the advice provided by the advisory panel of experts.[2] As a matter of fact, there is no indication that the FDA applied any of the procedures required by 21 C.F.R. Part 860 in undertaking to identify and classify these products as devices.

In addition, there does not appear to be any record or evidence in support of positions expressed by the FDA. For example, is it true that there were no test sample collection systems for drugs of abuse testing prior to May

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[2] Section 513 of the Act describes the classification process and requires the use of panels of experts to classify identified devices. This process requires deliberation by the panel during a public meeting in accordance with comprehensive regulations appearing in 21 C.F.R. Part 860.

28, 1976? What evidence does the FDA possess to support its statement that law enforcement use provides "other protections to ensure sample integrity and test accuracy that are not available in the home, workplace, insurance, and sports settings"? 63 Fed. Reg. at 10,793. In fact, there is reason to believe and support that sample integrity may be greatest in the home setting where the parent supervises collection of the sample.

If the FDA believes it has the authority to classify a product as a device, it must do so in accordance with applicable provisions of law and regulation supported by a record of evidence. This has not been done for this proposed rule.

**Policy**

The discussion of FDA policy in the preamble is confusing and contradicted by events subsequent to publication of the March 5, 1998 proposed rule.

Prior to the September 26, 1996 hearings of the House Subcommittee on Oversight and Investigations, the FDA did not have a documented policy for either drugs of abuse testing systems or test sample collection systems for use in the home setting. As a result, a variety of different types of products were available to the general public. Some of these had been cleared by the FDA and some had not. Yet, there is no evidence to support that availability of these products to the general public, with or without FDA clearance, created a hazard or an unreasonable risk of illness or injury.

The interim policy dated October 3, 1996 represented the FDA response to the September 26 House Subcommittee hearings. On February 6, 1997, FDA Deputy Commissioner for Policy, William B. Shultz, in testimony before the House Subcommittee, conveyed explicit commitments on behalf of the FDA, which have not been fulfilled. For example, Mr. Schultz stated that in developing a regulatory approach, the FDA is "seeking to ensure the reliability and accuracy of OTC drugs of abuse test systems, while minimizing the disruption to the marketplace, by proposing reasonable criteria and a transition period for conformance of the criteria." H.R. Rep. No. 4, 105th Cong. 1st Sess at 11 (1997). Mr. Schultz also stated that the new policy would be fully in place "in approximately two years." Id. at 12.

On September 25, 1997, the FDA Clinical Chemistry and Clinical Toxicology Devices Advisory Panel met to review issues related to drugs of abuse home testing and collection. This panel did not perform the activities required by 21 C.F.R. § 860.84 (e.g., questionnaire, supplemental data sheet, etc.). On the subject of approval criteria, the FDA representative expressed to the panel members that "It should be stated that the FDA has no position on this subject at this time." Surprisingly, there is no reference to this panel meeting in the preamble to the March 5, 1998 Federal Register proposal.

Finally, on December 30, 1998, the FDA issued a draft "Guidance for Industry" document applicable to "Kits for Screening Drugs of Abuse to Be Used By The Consumer." This document replaced a September 17, 1997 draft "Points to Consider" document.[3] The FDA expresses in the December 30, 1998 document that it represents "FDA's current thinking on Premarket Submissions . . .", but it clearly admonishes that this is a "Draft Guidance – Not for Implementation." Consequently, because the "not for implementation" December 30, 1998 document replaces the September 17, 1997 document, there is no FDA guidance document that is applicable to this subject.

The confusion created by the text of the preamble and FDA performance prior to and subsequent to the March 5, 1998 proposed rule represent adequate testimony to the need for withdrawal of this proposal.

**Application of Statute**

Whether provisions of the Act are applicable to tests and/or testing systems depends entirely on the intended use of a product. As discussed above with regard to jurisdiction, the FDA is distorting the device definition in an attempt to include products that are essential to maintain or determine

[3] This document was not mentioned in the March 5, 1998 proposed rule in the Federal Register.

compliance with laws that are enforced by local, state, and/or federal authorities. Neither these law enforcement/compliance uses nor those which relate to employment, school, insurance, or parental policies are intended for the diagnosis of a disease or other condition of a medical type. Rather, the intended use is to assure compliance for law enforcement and other societal reasons.

Where a product is intended for use as a device, the FDA has the responsibility to conform to those provisions of the Act that are applicable. If a device was in commercial distribution prior to May 28, 1976, the device must be classified through public use of an advisory panel and rulemaking. For devices that require premarket approval because the devices were not in commercial distribution prior to May 28, 1976, any reclassification as acknowledged by the FDA requires a similar opportunity for use of an advisory panel and public participation. This approach has not been applied to the products described in the proposed rule.

Apart from the failure of the FDA to follow "the same statutory provision and regulations that apply to reclassification of such devices in response to a petition," the proposal to regulate over-the-counter (OTC) products as restricted devices is peculiar. The purpose behind section 520(e) of the Act is to restrict availability and use of a device "to provide reasonable assurance of the safety and effectiveness of a device." In general, the FDA has limited its application of the restricted device provision of the Act to Class III devices that have been reviewed through the premarket approval process. These types of devices are usually limited to use by licensed practitioners, because they are used for a life sustaining or life supporting purpose.

At present, drugs of abuse products which are intended for an in vitro diagnostic use have not been identified by regulation as restricted devices. Yet, the FDA is attempting to identify as restricted devices OTC products which are not devices while at the same time exempting the product from premarket notification as a Class I device. This does not make sense.

Finally, if it is the FDA's intent to exempt pre and/or post May 28, 1976 in vitro diagnostic drugs of abuse devices from section 510, 519, or 520(f) of the Act, the FDA must receive "A recommendation of a panel . . ." as part of the classification. Again, the preamble to the proposed rule makes no

reference to any deliberation or recommendation by the panel for the classification of any in vitro diagnostic drugs of abuse device.

For the reasons stated above, the undersigned requests that the proposed rule be withdrawn or reproposed. If either request is granted, the undersigned further requests that the FDA acknowledge that products which are used for the purpose of assuring compliance with applicable laws relating to substance abuse (i.e., alcohol, prescription drugs, marijuana, etc.) are not subject to regulation by the FDA as devices. The undersigned further requests that the FDA initiate communication with other agencies of the federal government and offer its support to programs that are devoted to the reduction of substance abuse in the United States.

Sincerely,

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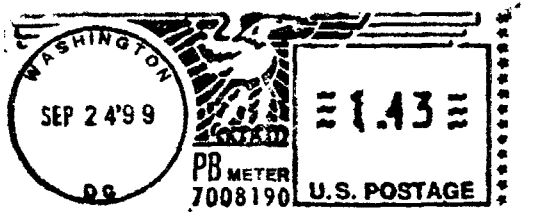


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